K130138

MAR 15 2013

Special 510(k) Summary

Introduction

In accordance with 21 CFR 807.81 (a)(3)(II) and CFR 807.92, Roche Diagnostics Corporation hereby submits official notification as required by Section 510(k) of the Federal Food, Drug and Cosmetics Act of our intention to market the device described in this Premarket Notification [510(k)].

The purpose of this Special 510(k) premarket notification is to request a claim extension for our ACCU-CHEK® Inform II System. The ACCU-CHEK Inform II System labeling will be modified to add another cleaning and disinfecting product for use with our device, Super Sani-Cloth® (EPA #9480-4).

The ACCU-CHEK Inform II system is a blood glucose monitoring system, a Class II medical device according to 21 CFR 862.1345. Super Sani-Cloth is a General Purpose Disinfectant, a Class I exempt product, according to 21 CFR 880.6890.

In building this submission, we followed FDA's Special 510(k) process and checklists. Also, we reviewed and adhered to the 2010 *Letter to Manufacturers of Blood Glucose Monitoring Systems Listed with the FDA*, regarding the proper validation of cleaning and disinfection methods.

The ACCU-CHEK Inform II System has not changed since its clearance on K121679. No technological, material, performance, or design changes to the ACCU-CHEK Inform II System have been implemented since its clearance on K121679. This submission pertains only to the performance of Super Sani-Cloth wipes for the effective cleaning and disinfecting of the ACCU-CHEK Inform II System housing and components.

In alignment with the approach utilized in our K121679 submission, the same cleaning and disinfecting test protocol was followed to evaluate the Super Sani-Cloth wipes for cleaning and disinfection of the same six distinct components of the ACCU-CHEK Inform II System. The corresponding test results demonstrate that the Super Sani-Cloth wipes are effective for the cleaning and disinfection of the device, in addition to the Clorox® Germicidal Wipes (EPA #67619-12).

1) Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250
Contact Person: Justin Davis
Date Prepared: March 14, 2013

Special 510(k) Summary, continued

2) Device name

Proprietary name: ACCU-CHEK Inform II System, consisting of

- Meter: ACCU-CHEK Inform II Meter
- Test Strip: ACCU-CHEK Inform II Test Strip
- Controls: ACCU-CHEK Inform II Control Solutions
- Linearity Kit: ACCU-CHEK Inform II Linearity Test Kit

Common name: whole blood glucose test system

Classification name: Glucose Dehydrogenase, Glucose (21 C.F.R.§862.1345)

Subsequent Product Code:

- LFR, Glucose Dehydrogenase
- NBW, System, Test, Blood Glucose, Over The Counter

510(k) History: K121679

3) Predicate device

The 510(k) history for the ACCU-CHEK Inform II System with Clorox Germicidal Wipes for cleaning and disinfection is K121679.

Please note that in this submission we did not make any changes or enhancements to the ACCU-CHEK Inform II System.

4) Device Description

No technological, material, performance, or design changes to the ACCU-CHEK Inform II System have been implemented since its clearance on K121679.

Thus, the Device Description for the ACCU-CHEK Inform II System remains the same as that presented and cleared in K121679.

This submission deals only with the performance of Super Sani-Cloth wipes for the effective cleaning and disinfection of the ACCU-CHEK Inform II System housing and components.

Please note that we intend to modify the ACCU-CHEK Inform II System labeling by adding the Super Sani-Cloth for cleaning and disinfection of the system, in addition to the Clorox Germicidal Wipes, which were previously cleared for this purpose on K121679. The Super Sani-Cloth will *not* replace the current Clorox Germicidal Wipe. Both wipes will be included in the product labeling.

Special 510(k) Summary, continued

5) Intended use	The ACCU-CHEK Inform II Test strip is for use with the ACCU-CHEK Inform II meter to quantitatively measure glucose (sugar) in venous whole blood, arterial whole blood, neonatal heelstick, or fresh capillary whole blood samples drawn from the fingertip as an aid in monitoring the effectiveness of glucose control. The system is not for use in diagnosis or screening of diabetes mellitus, nor for testing neonate cord blood samples. The ACCU-CHEK Inform II Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings. This system should only be used with single-use, auto-disabling lancing devices. The ACCU-CHEK Inform II Controls are intended for quality control performance checks on the ACCU-CHEK Inform II system with ACCU-CHEK Inform II test strips. The ACCU-CHEK Inform II Linearity Test Kit is intended for use for periodic verification of linearity of the ACCU-CHEK Inform II system using ACCU-CHEK Inform II test strips.

Special 510(k) Summary, continued

6) Substantial equivalence	No technological, material, performance, or design changes to the ACCU-CHEK Inform II System have been implemented since its clearance on K121679. In alignment with the approach utilized in our K121679 submission, the same cleaning and disinfecting test protocol was followed to evaluate the Super Sani-Cloth wipes for cleaning and disinfection of the same six distinct components of the ACCU-CHEK Inform II System. The corresponding test results demonstrate that the Super Sani-Cloth wipes are effective for the cleaning and disinfection of the device, in addition to Clorox Germicidal Wipes (previously cleared for use with the system on K121679). Robustness and effectiveness clearing and disinfecting testing on the ACCU-CHEK Inform II System for Super Sani-Cloths demonstrated that the device meets the performance requirements for its intended use. This also covers the components listed above, and is included within K121679. Overall, the data demonstrate that the ACCU-CHEK Inform II System operates in the same manner when cleaning and disinfecting occurs with the Super Sani-Cloth wipes.
7) Data demonstrating substantial equivalence	All components passed the cleaning and disinfection test protocol, based on the defined criteria. The data demonstrates that the Super Sani-Cloth is substantially equivalent to the Clorox Germicidal Wipe when used on the ACCU-CHEK Inform II System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 15, 2013

Roche Diagnostics Corporation
c/o Justin Davis
9115 Hague Rd.
Indianapolis, IN 46250

Re: k130138
Trade/Device Name: ACCU-CHEK Inform II Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, LFR
Dated: February 12, 2013
Received: February 13, 2013

Dear Mr. Davis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for

the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130138

Device Name: ACCU-CHEK Inform II Blood Glucose Monitoring System

Indications for Use:

The ACCU-CHEK Inform II Test strip is for use with the ACCU-CHEK Inform II meter to quantitatively measure glucose (sugar) in venous whole blood, arterial whole blood, neonatal heelstick, or fresh capillary whole blood samples drawn from the fingertip as an aid in monitoring the effectiveness of glucose control. The system is not for use in diagnosis or screening of diabetes mellitus, nor for testing neonate cord blood samples.

The ACCU-CHEK Inform II Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings. This system should only be used with single-use, auto-disabling lancing devices.

The ACCU-CHEK Inform II Controls are intended for quality control performance checks on the ACCU-CHEK Inform II system with ACCU-CHEK Inform II test strips.

The ACCU-CHEK Inform II Linearity Test Kit is intended for use for periodic verification of linearity of the ACCU-CHEK Inform II system using ACCU-CHEK Inform II test strips.

Prescription Use ___XX___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use __XX__ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Katherine Serrano

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k130138